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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,797	11/20/2001	Joseph S. Adorante	2732	1582

26822 7590 09/20/2004

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,797

Applicant(s)

ADORANTE ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

Claims 1-5 are pending and under consideration.

Response to Amendment

The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over WO 96/41166 (Tsien et al.) in view of US 5,981,268 (Kovacs et al.) and further in view of Gleitz et al. (1995), has been obviated by Applicant's amendment and is thus withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,686,193 (Maher et al.). The '193 patent has a priority date of July 10, 2000.

The claims are drawn to methods of identifying Na⁺ channel blockers by placing a cell comprising a Na⁺ channel and a K⁺ channel and a Na/K ATPase activity into a well, measuring

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T_m with a dye, adding the putative blocker, and stimulating an action potential with a current, and measuring the change in T_m optically, and wherein the compounds block transient Na⁺ channels. The claims are also drawn to methods wherein the cell is engineered to comprise the K⁺ and Na⁺ channels, and also blocking the Na⁺ pump with ouabain. The claims also encompass an apparatus for carrying out such measurements. Claims 1-4 are anticipated because the '193 patent discloses methods and systems of compound screening wherein the method comprises expressing the target ion channel in a population of host cells and placing a plurality of the host cells into each of a plurality of sample wells. A candidate drug compound is added to at least one of the plurality of sample wells; and the transmembrane potential of the cells is modulated with a repetitive application of electric fields so as to set the transmembrane potential to a level corresponding to a pre-selected voltage dependent state of the target ion channel. The '193 patent discloses methods of screening for blockers of voltage dependent Na⁺ channels, see column 54, lines 59-60, and also discloses that the method is advantageous for drug discovery where it provides the opportunity to screen for compounds that interact preferentially with one state, (i.e. use-dependent blockers). Specifically, use-dependent blockers of voltage-dependent sodium channels (column 55, lines 30-35). Claim 5 is anticipated because the '193 patent discloses an apparatus for high throughput screening (column 3, lines 5-17), wherein the apparatus comprises a plurality of wells having a high transmittance portion through which cells present in the wells are optically observable in an area of observation are each provided with two electrodes. A power supply is connected to the electrodes; wherein the power supply and the electrodes are configured to apply a series of electric fields to cells within the area of observation, the electric fields having a spatial variation of less than about 25% of a mean field

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intensity within the area of observation, the electric fields being effective to controllably alter the transmembrane potential of a portion of the cells. In addition, an optical detector is configured to detect light emanating from the wells through the high transmittance portion, and a data processing unit is provided to interpret the light emanating from the wells through the high transmittance portion as ion channel activity resulting from the transmembrane potential alterations (column 3, lines 19-28).

Conclusion

No claim is allowed.

References

The Office will no longer be supplying paper copies of U.S. Patents cited in Office Actions. Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Applicant may direct inquiries about the use of the Office's PAIR system to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
September 9, 2004


JOSEPH MURPHY
PATENT EXAMINER